K090168

510(k) Summary

MAR 1 2 2009

Trade Name: Azur Detachable 18

Generic Name: Vascular Embolization Device

Classification: Class II, 21 CFR 882.5950

Submitted By: MicroVention, Inc
75 Columbia
Aliso Viejo, California U.S.A.

Contact: Florin Truuvert

Predicate Device:

Number	Description	Clearance Date
K050954	MicroVention Inc., HydroCoil Embolic System (HES)	June 28, 2005

Device Description

The Azur Detachable 18 Coils are designed in the helical structure in various diameter and lengths. The coils are comprised of platinum alloy that are wound around the mandrels to form into the helical shape. The implant segment is then attached to the delivery pusher. The pusher is inserted into detachment controller which when activated detaches the coil from the delivery pusher. The detachment controller utilizes battery power to detach the coils from the delivery pusher. The coils are specified to be delivered through a microcatheter with a minimum inner diameter of 0.021" (0.053 mm).

Indication For Use

The Azur Detachable 18 Coil System is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature.

Verification and Test Summary Table

Bench Testing	Result
Visual Inspection	Met established criteria
Dimensional Measurement	Met established criteria
Tracking	Met established criteria
Repositioning- Deployment	Met established criteria
Placement - Stability	Met established criteria
Detachment Test	Met established criteria

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the Azur Detachable 18 line extension coils when compared with the predicate device MicroVention Azur Detachable 18 hydrocoil that was cleared to market under the MicroVention HydroCoil Embolic System (HES) K050954

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Use similar construction and material,
- Are packaged and sterilized using same material and processes.

In summary, the Azur coils described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2009

MicroVention, Inc.
% Florin Truuvert, RAC
Senior Director, Worldwide
Regulatory Affairs
75 Columbia, Suite A
Aliso Viejo, California 92656

Re: K090168
Trade/Device Name: Azur Detachable 18
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: II
Product Code: HCG
Dated: February 27, 2009
Received: March 2, 2009

Dear Florin Truuvert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090168

Indications for Use

510(k) Number (if known):

Device Name: Azur Detachable 18

Indications For Use:

The Azur Detachable Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and artiovenous fistula.

The coils are also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolization in the peripheral vasculature.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM March 11, 2009

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090168